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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,231	06/27/2000	Markus Pompejus	BGI-122CP	4162

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28 STATE STREET  
BOSTON, MA 02109

EXAMINER

MONSHIPOURI, MARYAM

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/26/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/604,231**

Applicant(s)  
**Pompejus et al.**

Examiner  
**Maryam Monshipouri**

Art Unit  
**1652**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 40-58 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-43 and 50-57 is/are allowed.
- 6) ☒ Claim(s) 44-49 and 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

Art Unit: 1652

Claims 1-2, 9-17, 25-33 and 39 have been canceled. Newly presented claims 40-58 are still at issue and are present for examination.

Applicants' arguments filed on 9/10/2002, paper No. 11, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 44-47, 49 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "phosphoethylpyruvate:sugar phosphotransferase system polypeptide" is confusing. It is not clear whether said term is referring to a specific and unique polypeptide or to a series of polypeptides involved in sugar transferase system. SEQ ID NO:2 in Table 1 of the specification is defined as Phopshotrnasferase enzyme II (EC 2.7.1.69).

**Therefore for examination purposes it is assumed that said term is referring to phosphotransferase enzyme II (E.C. 2.7.1.69).**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1652

4. Claims 48-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids encoding SEQ ID NO:2, does not reasonably provide enablement for either isolated DNA sequences that comprise merely 100 nucleotides of SEQ ID NO:2 or comprising sequences that can encode 100 contiguous amino acids of SEQ ID NO:2 with no function.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

Applicant is well aware that 100 nucleotides or even a DNA region encoding 100 contiguous amino acids of SEQ ID NO:2 is totally insufficient of encoding any products with function. The specification does not provide any information about the critical nucleotides in claimed DNA sequences that are in charge of encoding products with phosphotransferase activity. No examples of such critical nucleotide residues are provided either. Current state of prior art indicates that any DNA sequence that comprises merely 100 nucleotides of that encoding a full-length polypeptide or comprises a region encoding 100 contiguous amino acids of SEQ ID NO:2 is not necessarily capable of encoding any products with phosphotransferase activity.

Art Unit: 1652

Therefore due to lack of sufficient information and examples provided in the specification and due to unpredictability of prior art as to which nucleotides in claimed DNA sequences are in charge of assigning function to their expression products one of skill in the art has to go through the burden of undue experimentation in order to make or use the claimed DNA sequences as such the claimed go beyond the scope of the disclosure.

5. Claims 48-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 48 and 48 are drawn to a **genera** of nucleotides that either comprise merely 100 nucleotides of SEQ ID NO:2 or comprising sequences that can encode 100 contiguous amino acids of SEQ ID NO:2 , which have not been adequately described in the specification.

Applicant is well aware that 100 nucleotides or even a DNA region encoding 100 contiguous amino acids of SEQ ID NO:2 is totally insufficient of encoding any products with specific function. Some additional structural information about the composition of claimed DNA sequences beyond what is claimed is necessary which currently lacking in the specification. In addition, the specification does not contain any disclosure of the potential function of all DNA sequences that comprise merely 100 nucleotides of SEQ ID NO:2 or comprising sequences that can encode 100 contiguous amino acids of SEQ ID NO:2.

Art Unit: 1652

Therefore, The genera of cDNAs that comprise these above cDNA molecules is a large variable genera with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a **single species** of each claimed genus (namely SEQ ID NO:1) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

***Allowable Subject Matter***

**Claims 40-43, and 50-57 are allowed.** This is because an isolated nucleic acid molecules consisting of or comprising SEQ ID NO:1 or sequences capable of encoding SEQ ID NO:2 (sucrose phosphotransferase enzyme II, E.C. 2.7.1.69) are free of prior art. Further, the prior art does not teach or suggest preparing such specifically claimed DNA molecules. Hence, said molecules are also non-obvious. Since claimed DNA molecules are novel and non-obvious, vectors and host comprising said molecules are also novel and non-obvious.

Art Unit: 1652

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083.

The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.

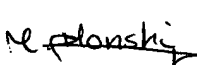
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Application/Control Number: 09/604,231

Page 7

Art Unit: 1652

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

  
Maryam Monshipouri, Ph.D.

Primary Examiner